

Claims:

- 1) A particulate composition comprising:
 - a) at least 50% of at least one structure forming amphiphile,
 - b) 0 to 40% of at least one structure swelling amphiphile, and
 - c) 2 to 20% of at least one dispersion stabilising polymeric amphiphile,

wherein all parts are by weight relative to the sum of the weights of a+b+c and wherein the composition comprises non-lamellar particles or forms non-lamellar particles when contacted with an aqueous fluid and wherein if component b) is 0% then component a) comprises at least two structure forming amphiphiles.
- 2) A particulate composition as claimed in claim 1, said composition comprising:
 - a) at least 50% of at least one structure forming amphiphile,
 - b) 2 to 40% of at least one structure swelling amphiphile, and
 - c) 2 to 20% of at least one dispersion stabilising polymeric amphiphile,

wherein all parts are by weight relative to the sum of the weights of a+b+c and wherein the composition comprises non-lamellar particles or forms non-lamellar particles when contacted with an aqueous fluid.
- 3) A composition as claimed in claim 1 or claim 2 wherein the amphiphilic components comprise at least 50% by weight amphiphiles having an aqueous solubility of less than 10^{-9} M at 25°C, relative to the total weight of components a+b+c.
- 4) A composition as claimed in claim 1 or claim 2 wherein the amphiphilic components comprise at least 70%, by weight amphiphiles having an aqueous solubility of less than 10^{-9} M at 25°C, relative to the total weight of components a+b+c.
- 5) A composition as claimed in any of claims 1 to 4 wherein component a) comprises at least one lipid component selected from phospholipids, glycolipids,

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and diglycerides.

6) A composition as claimed in any of claims 1 to 5 wherein component b) comprises at least one swelling agent selected from polyoxyethylene alkylethers, polyoxyethylene sorbitan fatty acid esters, polyoxyethylene fatty acid esters, polyoxyethylene castor oil derivateives or polyoxyethylene lipid derivatives.

7) . A composition as claimed in any of claims 1 to 6 wherein component c) comprises at least one polymeric agent selected from poloxamers, PEG-glyceroldioleate, PEG fatty acid esters or PEG-phospholipids.

8) A composition as claimed in any of claims 1 to 7 wherein said non-lamellar particles comprise L₃ phase and/or reversed hexagonal phase.

9) A composition as claimed in any of claims 1 to 8 additionally comprising at least one active agent.

10) A composition as claimed in any of claims 1 to 9 wherein component a) comprises a cationic lipid at a level of 1-10% by weight and the composition further comprises at least one nucleic acid active agent.

11) A composition as claimed in any of claims 1 to 10 wherein said non-lamellar particles have a particle size of 10 to 200 µm.

12) A composition as claimed in any of claims 1 to 11 wherein said non-lamellar particles are colloidal.

13) A composition as claimed in claim 12 wherein said non-lamellar particles are stable, both in terms of phase behaviour and particle size, to storage at room temperature for at least 10 days.

14) A composition as claimed in any of claims 1 to 13 which is non-haemolytic up to a concentration of 0.2% total amphiphile.

15) A composition as claimed in any of claims 1 to 14 which is non-haemolytic up to a concentration of 1% total amphiphile.

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- 16) A pharmaceutical formulation comprising at least one composition as claimed in any of claims 1 to 15 and at least one biologically tolerable carrier or excipient.
- 17) A kit suitable for establishing a biologically tolerable formulation of an active agent, said kit comprising at least one composition as claimed in any of claims 1 to 8